

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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	:	14 Civ. 1123 (NRB)
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IN RE INTERCEPT PHARMACEUTICALS,	:	ECF Case
INC. SECURITIES LITIGATION	:	
	:	
	:	
_____	X	

ANSWER AND JURY DEMAND

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Inc., Mark Pruzanski, and David Shapiro*

Pursuant to Federal Rules of Civil Procedure 8 and 12, Intercept Pharmaceuticals, Inc., Mark Pruzanski, and David Shapiro (collectively, the “Defendants”), hereby answer the Consolidated Amended Complaint (“Complaint”) filed by plaintiff George Burton on June 27, 2014. In responding to the Complaint, Defendants do not admit that they bear the burden of proving any of the matters set forth below, or the relevance of any of Plaintiff’s allegations. To the extent not explicitly admitted, Defendants deny all allegations of the Complaint.

No response is required to Plaintiff’s headings and titles in the Complaint, which consist solely of Plaintiff’s characterizations of this action. To the extent a response is required, Defendants deny each and every allegation contained therein.¹

Defendants deny each allegation except where specifically admitted, and in every respect deny liability, deny that they engaged in any improper conduct, and deny that Plaintiff is entitled to relief. Defendants respond to the specifically numbered allegations of the Complaint as follows:

1. No response is required to the allegations contained in paragraph 1, which purport to describe the Complaint, which speaks for itself. To the extent a response may be required, Defendants admit that this is an action that purports to be brought on behalf of anyone who purchased or otherwise acquired Intercept securities between January 9, 2014, and January 10, 2014, and deny the remaining allegations in paragraph 1.

2. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2, and therefore deny them.

I. INTRODUCTION AND OVERVIEW

3. Defendants deny the allegations in paragraph 3 except admit that Intercept is a pharmaceutical company that was founded in 2002, that its lead product candidate, obeticholic

¹ Defendants incorporate Plaintiff’s headings and titles in their Answer solely for clarity.

acid (“OCA”), is being developed for the treatment of liver diseases including nonalcoholic steatohepatitis (“NASH”) and primary biliary cirrhosis (“PBC”), and that, as of yet, none of its pharmaceutical products has received marketing approval or earned product revenue.

4. Defendants admit the first two sentences in paragraph 4. To the extent that the remainder of paragraph 4 purports to describe documents concerning the January 6, 2014 call, such documents speak for themselves, and therefore no response is required. Defendants deny that the description is a complete or accurate description of those documents or the phone call described therein.

5. Defendants deny the allegations in paragraph 5, except admit that on January 9, 2014 Intercept issued a press release and hosted a conference call with analysts and investors regarding the FLINT trial. To the extent that paragraph 5 purports to describe the January 9 press release and a transcript of the January 9 conference call, those documents speak for themselves, and therefore no response is required. Defendants deny that the description of the press release, the conference call, or its transcript is complete or accurate.

6. Defendants admit that Intercept’s stock price on the NASDAQ at the close of trading on January 8, 2014 was \$72.39, that the opening price on January 9 was \$231.89, that the closing price on January 10 was \$445.83, and that the combined volume for the trading days of January 9 and 10 was over 12 million shares. Defendants deny the remaining allegations in paragraph 6.

7. To the extent the allegations in paragraph 7 purport to describe the NIDDK press release, the January 12 Intercept press release, or emails between the NIDDK and Dr. Shapiro, those documents speak for themselves, and therefore no response is required. Defendants deny

that the description of those documents is complete or accurate. Defendants admit the remaining allegations in the first sentence in paragraph 7. Defendants deny the remaining allegations in the second sentence in paragraph 7, except admit that the NIDDK stated that, in response to numerous media requests, it would issue a press release. Defendants deny the remaining allegations in third sentence in paragraph 7, except admit that the NIDDK issued a press release. Defendants deny the remaining allegations in the fourth sentence in paragraph 7, except admit that that on Sunday January 12, 2014 Intercept issued a press release.

8. Defendants deny the allegations in paragraph 8, except admit that Intercept's stock price decreased by \$190.71 from its January 10 closing price to the close of trading on January 14 on volume that was higher than the pre-January 9 average volume.

9. To the extent the allegations in paragraph 9 purport to describe an "early morning media report" and an article from *The Wall Street Journal*, those documents speak for themselves, and therefore no response is required. Defendants deny that the description of those documents is complete or accurate. To the extent that they are deemed factual allegations, Defendants deny the remaining allegations in paragraph 9.

10. Defendants deny the allegations in paragraph 10, except admit that, on May 20, 2014, Intercept's stock price on the NASDAQ decreased from an opening price of \$240 per share to a closing price of \$223.34 per share.

II. JURISDICTION AND VENUE

11. No response is required to the allegations in paragraph 11, which purport to describe the Complaint, which speaks for itself.

12. Paragraph 12 states a legal conclusion to which no response is required.

13. Paragraph 13 states a legal conclusion to which to response is required.

14. Paragraph 14 states a legal conclusion to which no response is required.

III. THE PARTIES

15. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 regarding the residence or activities of Plaintiff Burton. Defendants deny the remaining allegations in paragraph 15.

16. Defendants admit the allegations in the first two sentences in paragraph 16. Defendants admit that Intercept become a publicly traded company through an initial public offering conducted in October 2012. . Defendants deny the remaining allegations in paragraph 16.

17. Defendants admit the allegations in paragraph 17.

18. Defendants admit that Mr. Pruzanski approved the Code of Conduct and Ethics. To the extent the allegations in paragraph 18 purport to describe the Code of Conduct and Ethics, that document that speaks for itself, and therefore no response is required. Defendants deny that the description of the document is complete or accurate. Defendants deny the remaining allegations in paragraph 18.

19. Paragraph 19 states legal conclusions to which no response is required. To the extent paragraph 19 is deemed to assert factual allegations, Defendants deny those allegations.

20. Defendants admit the allegations in paragraph 20.

21. Defendants admit that Dr. Shapiro approved the Code of Conduct and Ethics. To the extent the allegations in paragraph 21 purport to describe the Code of Conduct and Ethics, that document that speaks for itself, and therefore no response is required. Defendants deny that the description of the document is complete or accurate. Defendants deny the remaining allegations in paragraph 21.

22. Paragraph 22 states legal conclusions to which no response is required. To the extent paragraph 22 purports to contain factual allegations requiring a response, Defendants deny those allegations.

IV. BACKGROUND AND PRE-CLASS PERIOD EVENTS

A. Intercept and OCA

23. Defendants admit the allegations in paragraph 23.

24. Defendants admit the allegations in paragraph 24.

25. Defendants admit the allegations in paragraph 25.

B. The Market for OCA as a Treatment for NASH

26. Defendants admit the allegations in paragraph 26.

27. Defendants admit that there is a market for NASH treatment. To the extent the allegations in paragraph 27 purport to describe Intercept's public filings, those public filings speak for themselves, and therefore no response is required. To the extent that the allegations in paragraph 27 purport to describe press articles in *The New York Times* and *The Wall Street Journal*, those articles speak for themselves, and therefore no response is required. Defendants deny that the description of those documents is complete or accurate.

C. The NIDDK and the FLINT Trial

28. Defendants deny the allegations in the first sentence of paragraph 28, except they admit that OCA was subject to clinical trials to evaluate the drug prior to approval. Defendants admit the allegations in the second sentence of paragraph 28. Defendants deny the remaining allegations in paragraph 28, except admit that the NIDDK provided the majority of the resources for the FLINT trial. To the extent that these remaining allegations purport to describe public statements by any of those defendants, those statements speak for themselves, and therefore no response is required. Defendants deny that the description of the statements is complete or accurate.

29. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29.

30. No response is required to the allegations in paragraph 30, which purports to describe the content of a written statement by Intercept, which speaks for itself. Defendants deny that the description of the statement is complete or accurate.

31. To the extent that the allegations in paragraph 31 purport to describe the content of the CRADA, that document speaks for itself, and therefore no response is required. Defendants deny that the description of the CRADA is complete or accurate. The remaining allegations in paragraph 31 purport to set forth legal conclusions regarding FDA regulations, to which no response is required.

D. Intercept's Funding of OCA Trials

32. Defendants admit that Intercept completed follow-on public offerings in June 2013, and April 2014, and that these offerings raised \$61.4 million and \$183.5 million, respectively. To the extent that the allegations in paragraph 32 are inconsistent with that which has been admitted, they are denied. To the extent the allegations in paragraph 32 purport to describe Intercept's public SEC filings, those documents speak for themselves, and therefore no response is required. Defendants deny that the description of those documents is complete or accurate.

V. THE NIDDK INFORMS DEFENDANTS OF THE OCA EFFICACY AND SAFETY FINDINGS IN THE FLINT TRIAL

33. Defendants admit the allegations in paragraph 33.

34. Defendants lack knowledge of what constitutes an "official NIDDK record" and deny that the quoted material in paragraph 34 was such a record on that basis. To the extent that the allegations in paragraph 34 purport to describe publicly available NIDDK records, those documents speak for themselves, and therefore no response is required. Defendants deny that the description of those documents is complete or accurate. Defendants admit that there was a telephone call between Dr. Sherker and Dr. Shapiro regarding the FLINT trial on January 6, 2014.

35. Defendants admit that Dr. Shapiro sent Dr. Sherker an email on January 7, 2014. To the extent that the allegations of the remainder of paragraph 35 purport to describe a January 7, 2014 email from Dr. Shapiro to Dr. Sherker, that email speaks for itself, and therefore no response is required. Defendants deny that the description of that document is complete or accurate.

36. Defendants admit that Dr. Sherker responded to Shapiro's email on January 7, 2014. To the extent the allegations in paragraph 36 purport to describe a January 7, 2014 email

from Dr. Sherker to Dr. Shapiro, that email speaks for itself, and, therefore no response is required. Defendants deny that the description of that document is complete or accurate.

VI. DEFENDANTS' MISLEADING STATEMENTS AND MATERIAL OMISSIONS

37. Defendants admit the allegations in the first and second sentences of paragraph 37. To the extent the remaining allegations in paragraph 37 purport to describe a public filing, the filing speaks for itself, and therefore no response is required. Defendants deny that the description in paragraph 37 is complete or accurate.

38. No response is required to the allegations in paragraph 38, which purport to describe a press release, which speaks for itself. Defendants deny that the description of the document is complete or accurate. Defendants deny the remaining allegations in paragraph 38.

39. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the first two sentences in paragraph 39, but admit that the early stopping of the FLINT trial was covered by various media outlets. To the extent the allegations in paragraph 39 purport to describe an article published in *The New York Times*, the article speaks for itself, and therefore no response is required. To the extent such allegations are deemed factual allegations, Defendants lack knowledge or information as to whether the description of the article is complete or accurate.

40. Defendants deny the first sentence of paragraph 40, except admit that Intercept's stock price on the NASDAQ increased from a close of \$72.39 on January 8 to a close of \$275.87 on January 9, 2014, that the opening price of the stock on January 9 was \$231.89, and that trading volume for the trading day of January 9 was approximately 6.8 million shares. To the extent that

the allegations in paragraph 40 purport to describe articles published in *Xconomy*, *Dow Jones*, *FierceBiotech*, and *Money Morning*, the articles speak for themselves, and therefore no response is required. Defendants deny that the description is complete or accurate.

41. No response is required to the allegations in paragraph 41, which purports to describe a written transcript of a January 9, 2014 conference call with analysts and investors, which speaks for itself. Defendants deny that the description is complete or accurate.

42. No response is required to the allegations in paragraph 42, which purports to describe a written transcript of a January 9, 2014 conference call with analysts and investors, which speaks for itself. Defendants deny that the description is complete or accurate.

43. No response is required to the allegations in paragraph 43, which purports to describe an article published in *The Wall Street Journal*, which speaks for itself. Defendants deny that the description is complete or accurate.

44. Defendants deny the allegations in the first sentence of paragraph 44, except admit that Intercept common stock traded on the NASDAQ at an intraday high of \$497.00 per share on January 10, 2014. Defendants admit the second sentence of paragraph 44. Defendants deny the third sentence of paragraph 44, except admit that the closing price on the NASDAQ of Intercept stock increased by 61.6% between January 9 and January 10, 2014. To the extent that the remaining allegations in paragraph 44 purport to describe articles published in *Xconomy* and *MarketWatch*, the articles speak for themselves and therefore, no response is necessary. Defendants deny that the description is complete or accurate. Defendants admit that Intercept common stock traded at \$445.83 per share at the close of market on January 10, 2014. Defendants deny the remaining allegations contained in paragraph 44.

45. Defendants deny the allegations in paragraph 45.

VII. DISCLOSURE OF THE TRUTH ABOUT OCA AND THE FLINT TRIAL

46. No response is required to the allegations in paragraph 46, which purports to describe a January 10, 2014 email, which speaks for itself. Defendants deny that the description is complete or accurate.

47. No response is required to the allegations in paragraph 47, which purports to describe a January 10, 2014 email, which speaks for itself. Defendants deny that the description is complete or accurate .

48. No response is required to the allegations in paragraph 48, which purports to describe a January 10, 2014 email, which speaks for itself. Defendants deny that the description of that document is complete or accurate.

49. No response is required to the allegations in paragraph 49, which purports to describe a January 10, 2014 email, which speaks for itself. Defendants deny that the description of that document is complete or accurate.

50. Defendants admit that the NIDDK issued a statement to the media on January 10, 2014. To the extent the allegations purport to describe that statement, the statement speaks for itself, and therefore no response is required. Defendants deny that the description is complete or accurate. Defendants deny the remaining allegations of paragraph 50.

51. No response is required to the allegations in paragraph 51, which purport to describe an article published in *The Wall Street Journal*, which speaks for itself. Defendants deny that the description is complete or accurate.

52. To the extent that the allegations in paragraph 52 purport to describe an article published in *The Wall Street Journal*, the article speaks for itself, and therefore no response is required. Defendants deny that the description is complete or accurate. Defendants deny the remaining allegations of paragraph 52.

53. Defendants admit that Intercept issued a press release and filed a Form 8-K with the SEC on January 12, 2014. To the extent that the allegations in paragraph 53 purport to describe that press release or public filing, those documents speak for themselves, and therefore no response is required. Defendants deny that the description is complete or accurate.

54. Defendants admit that Intercept's common stock decreased on the NASDAQ from an opening price on January 13, 2014 of \$339.87 per share to a closing price on January 14, 2014 of \$255.12 per share, and admit that the volume during that period was higher than the stock's average daily volume prior to the purported Class Period. To the extent that the allegations in paragraph 54 purport to describe articles published in *The Wall Street Journal* and *MarketWatch*, the articles speak for themselves, and therefore no response is required. Defendants deny that the description is complete or accurate. Defendants deny the remaining allegations of paragraph 54.

55. No response is required to the allegations in paragraph 55, which purports to describe a May 20, 2014 written article in *TheStreet*, which speaks for itself. Defendants deny that the description is complete or accurate. To the extent that the description of the article referenced in paragraph 55 is deemed to constitute factual allegations, Defendants deny those allegations. Defendants deny the remaining allegations in paragraph 55.

56. Defendants admit that on May 20, 2014, Intercept's stock price decreased on the NASDAQ by \$36.66 per share to close at \$223.34, on trading volume of over 1.6 million shares.

To the extent that the allegations in paragraph 56 purport to describe articles published by the *TheStreet* and Zacks Equity Research, the articles speak for themselves, and therefore no response is required. Defendants deny that the description is complete or accurate. To the extent that the description of the articles in paragraph 56 are deemed factual allegations, Defendants deny those allegations. Defendants deny the remaining allegations in paragraph 56.

57. No response is required to the allegations in paragraph 57, which purports to describe an article published in *The Wall Street Journal*, which speaks for itself. Defendants deny that the description is complete or accurate. To the extent that the description of the article in paragraph 57 can be construed as factual allegations, Defendants deny those allegations. Defendants deny the remaining allegations in paragraph 57.

VIII. LOSS CAUSATION/ECONOMIC LOSS

58. Defendants deny the allegations in paragraph 58.

59. Defendants deny the allegations in paragraph 59.

60. Defendants deny the allegations in paragraph 60.

61. Defendants deny the allegations in paragraph 61.

62. Defendants deny the allegations in paragraph 62.

63. Defendants deny the allegations in paragraph 63.

IX. APPLICABILITY OF THE PRESUMPTION OF RELIANCE

64. Paragraph 64 states a legal conclusion to which no response is required.

65. To the extent paragraph 65 states a legal conclusion, no response is required. To the extent that paragraph 65 purports to contain factual allegations requiring a response, Defendants deny the allegations in paragraph 65.

X. CLASS ACTION ALLEGATIONS

66. No response is required to the allegations contained in paragraph 66, which purports to describe the Complaint, which speaks for itself.

67. To the extent paragraph 67 states a legal conclusion, no response is required. To the extent that paragraph 67 purports to contain factual allegations requiring a response, Defendants deny the remaining allegations in paragraph 67.

68. To the extent paragraph 68 states a legal conclusion, no response is required. To the extent that paragraph 68 purports to contain factual allegations requiring a response, Defendants deny the remaining allegations in paragraph 68.

69. Defendants deny the allegations in paragraph 69.

70. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70.

71. To the extent paragraph 71 states a legal conclusion, no response is required. To the extent that paragraph 71 purports to contain factual allegations requiring a response, Defendants deny the allegations in paragraph 71.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

72. Defendants restate their responses to all preceding paragraphs as if fully set forth here. No response is required to the remaining allegations in paragraph 72, which purport to describe the Complaint, which speaks for itself.

73. Defendants deny the allegations in paragraph 73.

74. Defendants deny the allegations in paragraph 74.

75. Defendants deny the allegations in paragraph 75.

76. To the extent paragraph 76 states a legal conclusion, no response is required. To the extent that paragraph 76 purports to contain factual allegations requiring a response, Defendants deny the allegations in paragraph 76.

77. Defendants deny the allegations in paragraph 77.

78. Defendants deny the allegations in paragraph 78.

79. Defendants deny the allegations in paragraph 79.

80. Defendants deny the allegations in paragraph 80.

81. Defendants deny the allegations in paragraph 81.

COUNT II

**For Violation of § 20(a) of the Exchange Act
Against All Defendants**

82. Defendants restate their responses to all preceding paragraphs as if fully set forth here. No response is required to the remaining allegations contained in paragraph 82, which purport to describe the Complaint, which speaks for itself.

83. To the extent paragraph 83 states a legal conclusion, no response is required. To the extent that paragraph 83 purports to contain factual allegations requiring a response, Defendants deny the allegations in paragraph 83.

84. To the extent paragraph 84 states a legal conclusion, no response is required. To the extent that paragraph 84 purports to contain factual allegations requiring a response, Defendants deny the allegations in paragraph 84.

85. Defendants deny the allegations in paragraph 85.

With respect to all paragraphs in the Complaint in which Plaintiff prays for relief, Defendants deny that Plaintiff is so entitled under law.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Defendants demand a jury trial of all issues triable by jury under applicable law.

AFFIRMATIVE DEFENSES

Defendants do not waive any affirmative defenses and reserve the right to assert any and all affirmative or other defenses that may be available after reasonable discovery.

First Affirmative Defense

The Complaint fails to allege facts sufficient to state a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiff has failed to plead his claims with requisite particularity pursuant to Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act of 1995.

Third Affirmative Defense

Every act or omission alleged in the Complaint was done or omitted in good faith and in conformity with the rules and regulations of the Securities and Exchange Commission, and therefore, pursuant to Section 23(a) of the Securities Exchange Act of 1934, there is no liability for any act or omission so alleged.

Fourth Affirmative Defense

Under the Private Securities Litigation Reform Act of 1995, Plaintiff's damages (and those of members of the putative class), if any, must be reduced in whole or in part pursuant 15 U.S.C. § 78u-4(e).

Fifth Affirmative Defense

The Defendants are not liable, as any alleged misstatements or omissions made or caused to be made by them were based in good faith and in reasonable reliance on information provided by third parties.

Sixth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged damages (and those of members of the putative class), if any, were caused in whole or part by a superseding or intervening cause.

Seventh Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because he has failed to mitigate his alleged damages and failed to exercise due diligence in an effort to mitigate his alleged damages.

Eighth Affirmative Defense

The Defendants are not liable, as Plaintiff's damages (and those of members of the putative class), if any, should be reduced, diminished and/or eliminated under the proportionate liability provisions of Section 21D(f)(2)(B) and 21(D)(f)(3) of the Securities Exchange Act of 1934 to reflect only the Defendants' percentage of responsibility (if any).

Ninth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff failed to exercise due care or otherwise acted recklessly.

Tenth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, because he assumed the risks disclosed in the public filings and other public disclosures made by Defendants or others.

Eleventh Affirmative Defense

Plaintiff is not entitled to any recovery because Plaintiff did not exercise reasonable care to discover the facts relating to the alleged misstatements or omissions.

Twelfth Affirmative Defense

Plaintiff is not entitled to application of the fraud-on-the market presumption.

Additional Defenses, Counterclaims, Cross-Claims, and Third-Party Claims

Defendants reserve the right to raise any additional defenses, counterclaims, cross-claims, and third-party claims not asserted that may become apparent through discovery or other investigation.

WHEREFORE, Defendants respectfully request that this Court dismiss the Complaint and Plaintiff's claims, enter judgment in favor of the Defendants and against Plaintiff, award Defendants the reasonable attorneys' fees, costs, and expenses they have incurred in the defense of this action, and grant Defendants any additional relief that is fair and appropriate.

Dated: April 13, 2015

Respectfully submitted,

**INTERCEPT PHARMACEUTICALS, INC.,
MARK PRUZANSKI, AND DAVID SHAPIRO,**

By their Attorneys,

/s/ Michael G. Bongiorno

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